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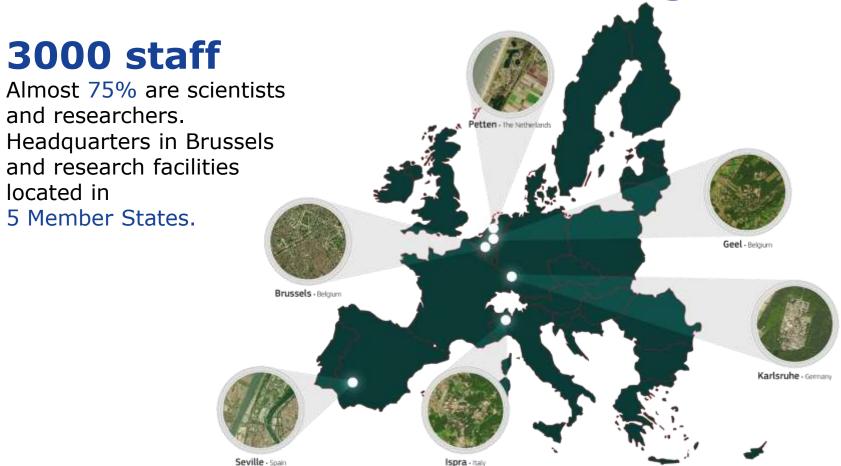
The NANoREG Toolbox for the safety assessment of nanomaterials

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The Joint Research Centre at a glance







NANoREG project

- European FP7 project 2013–17, "A common European approach to the regulatory testing of Manufactured Nanomaterials"
- JRC led WP1, "Scientific answers to regulatory issues"
- Outputs of NANoREG WP1 include these main project outcomes:
 - NANoREG Framework for the safety assessment of nanomaterials (contributions from a large number of project partners, coordinated and edited by JRC)
 - NANoREG Toolbox for the safety assessment of nanomaterials (dataset compiled by JRC)







The Framework and the Toolbox

- The Framework and the Toolbox are linked in structure and content
- Framework: .pdf report published in April 2017, DOI: 10.2760/245972
- Toolbox: dataset first published in September 2017, update published in January 2018

DOI: 10.2760/332209 (short introductory.pdf)

http://data.europa.eu/89h/jrc-nano-ehs-ring-nanoreg-tb

(.zip file containing two Excel® workbooks)

- Released at the JRC Data Catalogue
- Under Creative Commons ShareAlike license (CC BY-SA 4.0)







EU context vs. other regions

- Both the NANoREG Framework and the NANoREG Toolbox revolve mostly around European Union's regulatory definitions and requirements concerning nanomaterials (mainly under REACH regulation)
- However...
 - The basic risk assessment paradigm is universal
 - Regulatory information/testing requirements for chemicals in different countries are increasingly being harmonized by e.g. the implementation of the United Nations' Globally Harmonized system (GHS)
 - Testing methodology suited for NMs is being internationally harmonized by OECD, standardised by (e.g.) ISO



The Toolbox is applicable also outside the EU!







Framework structure (part I)

1. INTRODUCTION

PART I – CURRENT REGULATORY CONTEXT FOR NANOMATERIALS

- 2. DEFINITION OF NANOMATERIAL IN A REGULATORY CONTEXT
- 3. SAFETY ASSESSMENT OF NANOMATERIALS UNDER REACH
 - 3.1. SUBSTANCE IDENTIFICATION
 - 3.2. INFORMATION REQUIREMENTS
 - 3.3. RULES FOR ADAPTATION OF THE STANDARD TESTING
 - 3.4. HAZARD ASSESSMENT
 - 3.5. EXPOSURE ASSESSMENT
 - 3.6. RISK CHARACTERISATION







Framework structure (part II)

PART II – FORWARD-LOOKING STRATEGIES FOR NANOMATERIALS

4. NANOSPECIFIC PRIORITISATION AND RISK ASSESSMENT

5. SAFE-BY-DESIGN

6. LIFE CYCLE ASSESSMENT

7. TAKE-HOME MESSAGES AND FINAL CONSIDERATIONS

ANNEXES I-V







The idea of the NANoREG Toolbox

- Supports the Framework by identifying & inventorying tools for the different steps and options of NM safety assessment
 - Toolbox .xls workbook: tools publicly available, ready to use
 - Prospective tools .xls workbook: tools promised to become available in the short or medium term
- The workbooks are organised into worksheets that correspond to the sections of the NANoREG Framework
 - E.g. "3.5 Exposure assessment", "6 Life Cycle Analysis"
- Tools within each worksheet are categorised according to:
 - Purpose
 - Type
 - Regulatory [acceptance] status





NAN SREG

Concepts: "tool"

"An experimental, computerised, or decision procedure used for generating, collecting, assessing, and/or storing a certain type of output"

Gottardo, S. et al. 2016. NANoREG harmonised terminology for environmental health and safety assessment of nanomaterials, EUR 27808. DOI: 10.2788/71213

- Toolbox tools...
 - ...must be directly accessible
 - ...may require registration or payment
- These are **not** considered tools:
 - Technical instruments
 - Services (provided e.g. by consultants)







How tools were gathered

- Tools mentioned in the NANoREG Framework
- Tools suggested by NANoREG partners
- Tools (being) developed by nanosafety research projects
- Reviews and reports about existing tools
- Literature searches
- Web searches

All useful tools that were found were recorded – not only from European sources or context!





NAN SREG

Toolbox in practice

- Each worksheet corresponds to a section of the Framework
- Each row is a tool record
- Each column provides an information item about the tool





NAN SREG

Information items recorded

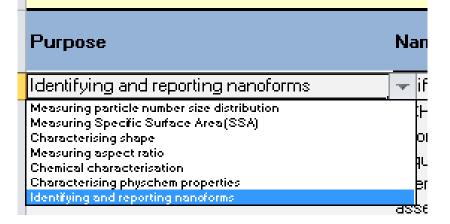
- Purpose (drop-down menu of options)
- Name of the tool
- Type (drop-down menu)
- Regulatory status (drop-down menu)
- Description
- Documented applications
- Other information
- Project or organisation
- Publication(s)
- Link to a relevant website





Concepts: "purpose" of tool

- Typically, purpose = endpoint served by the listed tool
- A drop-down menu with fixed options
 - Menu developed separately for each section of the Toolbox
 - Options are partly based on regulatory requirements or guidance, partly pragmatic



Purpose	Nar
Characterising consumer exposure	₩ I
Developing Exposure Scenarios (ES) Characterising occupational exposure	
Characterising consumer exposure Characterising environmental exposure	
Qualitative exposure characterisation Exposure / release simulation	
Controlling exposure Other	





Concept: "type" of tool

- Experimental protocol e.g. SOP/guideline for conducting a toxicological experiment or characterising a physicochemical property
- Model e.g. a predictive algorithm of exposure or release into the environment, or a (Q)SAR application
- Decision support tool e.g. a checklist or decision tree that helps to define a testing strategy, or a software system that provides relevant information for decision-making
- Guidance a document prepared by a regulatory authority or international organisation to communicate official recommendations for implementing regulatory requirements or performing specific testing
- Report a document by a research group or a public authority, giving independent advice on how to perform specific research activities or implement specific regulatory requirements
- Data management tool a tool/system for data storage, handling or analysis
- Repository a source of reference materials for analysis or testing





Concepts: "regulatory status"

The regulatory acceptance level of the tool

Disclaimer: the 'regulatory status' is provided purely for informative and user guidance purposes in the Toolbox files, and it does not engage any responsibility on its accuracy from the JRC or anyone else in the NANoREG project

- Research product a research outcome that has not been tested / validated / standardised / harmonised for regulatory purposes (default option)
- Validated has undergone a formal interlaboratory validation procedure
- Harmonised has undergone a formal harmonisation process at OECD level
- Standardised has undergone a formal standardisation process at e.g. ISO or CEN level
- Regulatory document the tool is a document developed by a regulatory or competent authority, and it therefore has high regulatory relevance
- Not applicable none of the options above properly apply





Nature of the recorded information NAN

- The primary source of information about each tool: relevant publications, documentation and promotional material by the developers of the tool
- Any publications (e.g. reviews) analysing or applying the tool could also be used
- Prospective tools:
 - Project websites, newsletters etc.
 - Conference presentations, posters
 - Direct contact with the developers
- Expert judgment (of Toolbox developers and colleagues)
- Note: the NANoREG Toolbox has its own criteria for
 - the correct location(s) of a tool within the Toolbox
 - assigning each tool a type, a regulatory status etc.







November 2017 update

- Original dataset is from August 2017 (published in September)
- New version:
 - Each combination of tool identity, purpose, type and regulatory status is now a separate record (if the same tool e.g. serves several different purposes, it is also covered by several records)
 - Content updated, supplemented and corrected, including new records
- Reasons:
 - Easier to search for tools (e.g. by purpose) by using MS Excel Filtering and Sorting functions
 - Easier to handle the dataset
- Available online since January 10, 2018





NANoREG Toolbox contents

- November 2017 updated version: > 550 unique tools in total
- > 500 unique tools referenced in the 'Toolbox' (current tools)
 - 75 % are nanospecific
 - 18 % are NANoREG products
 - Most common type of tool is experimental protocol
 (58 %)
 - Most common regulatory status is research product (61 %)
- 29 tools (all unique and nanospecific) recorded as 'prospective tools'







Uses of the NANoREG Toolbox

- Entry portal to currently available tools
 - Can be browsed or searched using various Excel functions
 - Information provided about each tool helps to find appropriate tool(s) for a specific purpose, if available
 - Web link and/or literature reference provides access to each tool
- Inventory of what is currently available (Toolbox) or is expected to become available relatively soon (Prospective tools)
- Basis for a potential proper database
 - A Wiki based solution would give the users the opportunity to supplement and update the contents





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